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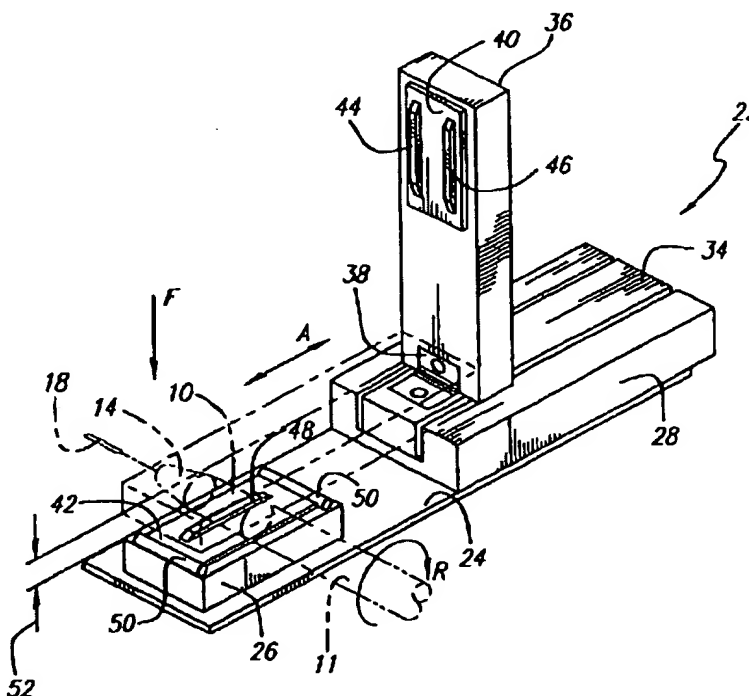
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(54) Title: METHOD AND APPARATUS FOR A STENT CRIMPING DEVICE

(57) Abstract

A stent crimping tool (22) for firmly and uniformly crimping a stent (10) onto a balloon catheter (14) is constructed from a stationary plate (26) and a sliding platform (28) connected to the stationary plate (26) and slidable linearly relative thereto. A closing plate (36) is hinged to the sliding platform (28) so that it at least partially overlies the stationary plate (26) in a down position, and swings away from the stationary plate (26) to an up position, whereby the stent (10) already having been slightly hand crimped onto the balloon catheter (14) is placed on the stationary plate (26) from a lateral position, and the closing plate (36) is moved to the down position to hold the stent (10) between the closing plate (36) and the stationary plate (26) so that an external force on the closing plate (36) as well as translational motion of the closing plate together crimp the stent (10) onto the balloon catheter (14). The surfaces engaging the stent (10) may be covered by elastomeric pads (40, 42) having ridges (44, 46, 48) corresponding in location to respective rings or cylindrical elements (12) of the stent (10).



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METHOD AND APPARATUS FOR A STENT CRIMPING DEVICE

BACKGROUND OF THE INVENTION

The present invention relates to a method and apparatus for loading a tubular graft, such as a stent, onto the distal end of a catheter assembly of the kind used, for example, in percutaneous transluminal coronary angioplasty (PTCA) or percutaneous transluminal angioplasty (PTA) procedures.

5 In typical PTCA procedures, a guiding catheter is percutaneously introduced into the cardiovascular system of a patient through the brachial or femoral arteries and advanced through the vasculature until the distal end of the guiding catheter is in the ostium. A guide wire and a dilatation catheter having a balloon on the distal end are introduced through the guiding catheter with the guide wire sliding within
10 the dilatation catheter. The guide wire is first advanced out of the guiding catheter into the patient's coronary vasculature and the dilatation catheter is advanced over the previously advanced guide wire until the dilatation balloon is properly positioned across the arterial lesion. Once in position across the lesion, a flexible and expandable balloon is inflated to a predetermined size with a radiopaque liquid
15 at relatively high pressures to radially compress the atherosclerotic plaque of the lesion against the inside of the artery wall and thereby dilate the lumen of the artery. The balloon is then deflated to a small profile so that the dilatation catheter can be withdrawn from the patient's vasculature and the blood flow resumed through the dilated artery. As should be appreciated by those skilled in the art, while the above-
20 described procedure is typical, it is not the only method used in angioplasty.

In angioplasty procedures of the kind referenced above, restenosis of the artery may develop over time, which may require another angioplasty procedure, a surgical bypass operation, or some other method of repairing or strengthening the area. To reduce the likelihood of the development of restenosis and to strengthen
25 the area, a physician can implant an intravascular prosthesis for maintaining vascular patency, commonly known as a stent, inside the artery at the lesion. The

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stent is crimped tightly onto the balloon portion of the catheter and transported in its delivery diameter through the patient's vasculature. At the deployment site, the stent is expanded to a larger diameter, often by inflating the balloon portion of the catheter. The stent also may be of the self-expanding type.

5 Because the catheter and stent travel through the patient's vasculature, and often through the coronary arteries, the stent must have a small delivery diameter and must be firmly attached to the catheter until the physician is ready to implant it. Thus, the stent must be loaded onto the catheter so that it does not interfere with delivery, and it must not come off the catheter until it is implanted.

10 In procedures where the stent is placed over the balloon portion of the catheter, it is necessary to crimp the stent onto the balloon portion to reduce its diameter and to prevent it from sliding off the catheter when the catheter is advanced through the patient's vasculature. Non-uniform crimping can result in sharp edges being formed along the now uneven surface of the crimped stent.

15 Further, non-uniform stent crimping may not achieve the desired minimal profile for the stent and catheter assembly. Where the stent is not reliably crimped onto the catheter, the stent may slide off the catheter and into the patient's vasculature prematurely as a loose foreign body, possibly causing blood clots in the vasculature, including thrombosis. Therefore, it is important to ensure the proper crimping of a

20 stent onto a catheter in a uniform and reliable manner.

 This crimping is often done by hand, which can be unsatisfactory due to the uneven application of force resulting in non-uniform crimps. In addition, it is difficult to visually judge when a uniform and reliable crimp has been applied.

 Some self-expanding stents are difficult to load by hand onto a delivery

25 device such as a catheter. Further, the more the stent is handled the higher the likelihood of human error, which is antithetical to a properly crimped stent. Accordingly, there is a need in the art for a device for reliably crimping a stent onto a catheter.

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There have been attempts at devising a tool for crimping a stent onto a balloon delivery catheter. An example of such a tool comprises a series of plates having substantially flat and parallel surfaces that move in a rectilinear fashion with respect to each other. A stent-carrying catheter is disposed between these surfaces, which surfaces crimp the stent onto the outside of the catheter by relative motion and applied pressure. The plates have multiple degrees of freedom and may have force-indicating transducers to measure and indicate the force applied to the catheter during crimping of the stent.

Another stent-loading tool design is comprised of a tubular member which houses a bladder. The tubular member and bladder are constructed to hold a stent that is to be crimped onto a balloon catheter assembly. Upon placement of the stent over the balloon portion of the catheter, a valve in the loading tool is activated to inflate the bladder. The bladder compresses the stent radially inward to a reduced diameter onto the balloon portion of the catheter to achieve a snug fit. In this way, the stent is crimped onto the distal end of a balloon catheter with a minimum of human handling. The foregoing stent crimping tools are disclosed in, for example, U.S. Patent Nos. 5,437,083 and 5,546,646 to Williams et al.

Yet another stent crimping tool is manufactured by C.R. Bard, Inc. under the trade name BARD XT, which is actually a stent loader. It is constructed from a rigid, tubular body with a ball at one end connected to a plurality of long, thin strips passing through the tubular body. An uncrimped stent is placed over the plurality of long, thin strips, which hold the stent in an expanded state. The balloon portion of a catheter is inserted into the cylindrical space formed by the plurality of strips. When the user pulls the ball while holding the tubular body against the stent, the strips are slid from beneath the stent and the stent is transferred onto the balloon portion.

Still another conventional stent crimping tool is manufactured by Johnson & Johnson, Inc. and has an appearance similar to that of a hinged nutcracker. Specifically, the tool is comprised of two hand-operated levers that are hinged at

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one end and which are gripped in the palm of the hand at the opposite end. A cylindrical opening holding a crimping tube is provided through the mid-portion of the tool to receive therein a stent loaded onto a balloon catheter. The crimping operation is performed by the user squeezing the handle, thereby pressing the crimping tube which, in turn, pinches the stent onto the balloon catheter.

While the prior art devices are suitable for crimping stents onto balloon catheters, some suffer from problems such as non-uniform crimping forces, resulting in non-uniform crimps. Consequently, there is a need for improved stent crimping tools for use by physicians in a catheterization laboratory who desire to consistently crimp stents onto balloon catheters.

SUMMARY OF THE INVENTION

Both PTCA and PTA procedures have become commonplace in treating stenoses or lesions in blood vessels and coronary arteries. In approximately 35 to 40 percent of the procedures, restenosis may develop requiring a further angioplasty, atherectomy or bypass procedure to return the patency of the vessel. Intravascular stents are now being deployed after PTCA and PTA procedures, and after atherectomies, in order to help prevent the development of restenosis. Importantly, such stents, mounted on the balloon portion of a catheter, must be tightly crimped to provide a low profile delivery diameter, and to make certain that the stent stays on the balloon until the balloon is expanded and the stent is implanted in the vessel.

Embodiments of the present invention are directed to a crimping tool that repeatedly can provide a uniform and tight crimp to ensure the low profile diameter of the stent on the balloon portion of the catheter, and to ensure that the stent remains firmly attached until it is implanted in the vessel by expanding the balloon. Specifically, the present invention is directed to a stent crimping tool for crimping a stent onto a balloon catheter. In a preferred embodiment, the stent crimping tool

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comprises a stationary plate, a sliding platform connected to the stationary plate which is slidable linearly relative thereto, a closing plate that is hinged to the sliding platform so that the closing plate at least partially overlies the stationary plate in a down position, and swings away from the stationary plate to an up position, whereby the stent having been loaded onto the balloon catheter is placed on the stationary plate from a lateral position, and the closing plate is moved to the down position to hold the stent between the closing plate and the stationary plate so that an external force on the closing plate and translational motion of the closing plate crimp the stent onto the balloon catheter. In this manner, the pinching pressure of the stationary plate against the closing plate generates a radially inward force on the stent; the translational motion of the sliding platform effectively rolls the stent-catheter assembly to evenly distribute the crimping force for a homogeneous crimp.

In an exemplary embodiment, the closing plate and the stationary plate have facing surfaces that include contoured pads that help grip the stent. Further, the pads optionally can have ridges, channels, or other contours that correspond to specific locations on the stent. For example, when a stent manufactured by Advanced Cardiovascular Systems, Inc. under the trademark MULTI-LINK is the device to be crimped, ridges in the pads can be situated to coincide with the locations of the proximal and distal rings of the stent. A ridge may be provided on the pads to grip a mid-length ring as well. These pinch points help insure uniform reduction in the diameter of the stent during the crimping procedure. The pinch or grip points also help stabilize the stent-catheter assembly during the crimping operation. Of course, the number, location, and shape of each grip point can be varied as needed.

In a preferred embodiment, a spacer having a cylindrical shape is positioned on the stationary plate to set a predetermined gap between the stationary plate and the closing plate in the down position. That gap therefore corresponds with the diameter of the spacer. Such spacers work as gap controllers to obtain repeatable

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and consistent diameters on the crimped stents. Further, the spacers prevent over-crimping, which potentially may produce pinholes in the balloon catheter.

In alternative embodiments, a mandrel can be inserted into the balloon catheter to provide some level of internal support during the crimping process.

- 5 Moreover, it is recommended that the surface that is directly in contact with the stent during the crimping procedure be slightly softer than the stent material to allow for yield. Elastomer-type materials with higher durometers may be considered.

- 10 When the stent is inserted into the stationary plate from a lateral position, a stop or riser formed into the stationary plate maintains proper alignment of the stent-catheter assembly relative to the crimping tool. The stent abuts against the stop so that the stent-catheter assembly is not inserted too far or not far enough into the tool.

- Accordingly, embodiments of the present invention is very simple to operate. With few moving parts and use of a spacer to set the gap between the stationary
15 plate and closing plate, it is possible to consistently and repeatably crimp stents onto balloon catheters. Loading and unloading the stent-catheter assembly into and out of a crimping tool according to the present invention can be accomplished quickly because the closing plate swings out of the way.

- Embodiments of a crimping tool in accordance with the present invention is
20 highly useful to cardiologists, for example. Such physicians often are concerned with proper deployment of the stent within the patient that it is desirable to have a consistently and reliably crimped stent. A crimping tool according to the present invention further is a time saver, because the stent crimping procedure can be performed fairly efficiently and quickly. These and other advantages a stent
25 crimping tool according to the present invention will become apparent from the following detailed description thereof when taken in conjunction with the accompanying exemplary drawings.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a side elevational view, partially in section, depicting a stent that has been crimped onto a balloon portion of a delivery catheter and disposed within a vessel.

5 FIG. 2 is a perspective view of a preferred embodiment of the present invention showing a stent crimping tool wherein the closing plate is in an up position and the position of the stent-catheter assembly is indicated by dashed lines.

FIGS. 3A and 3B are perspective views showing alternative embodiments of a pad having ridges and a pad having channels, respectfully, which ridges and
10 channels are helpful in gripping the stent.

FIG. 4 is a perspective view of a slide having a dove tail to which a closing plate is attached.

FIG. 5 is a perspective view of the platform a preferred embodiment of the present invention showing a channel designed to receive the dove tail of the slide
15 shown in FIG. 4.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 illustrates an intravascular stent 10 which is mounted onto a delivery catheter 11. The stent 10 generally comprises a plurality of radially expandable rings or cylindrical elements 12 disposed coaxially and interconnected by members
20 13 disposed between adjacent cylindrical elements 12. The delivery catheter 11 has an expandable portion or a balloon 14 for expanding the stent 10 within the coronary artery 15 or other vessel such as the saphenous veins, carotid arteries,

arteries, and veins. The artery 15, as shown in FIG. 1, has a dissected lining 16 which has occluded a portion of the arterial passageway.

The delivery catheter 11 onto which the stent 10 is mounted is essentially the same as a conventional balloon dilatation catheter for angioplasty procedures. The balloon 14 may be formed of suitable materials such as polyethylene, polyvinyl chloride, polyethylene terephthalate and other like polymers. In order for the stent 10 to remain in place on the balloon 14 during delivery to the site of the damage within the artery 15, the stent 10 is compressed onto the balloon 14.

An optional retractable protective delivery sleeve 20 may be provided to further ensure that the stent 10 stays in place on the balloon 14 of the delivery catheter 11 and to prevent abrasion of the body lumen by the open surface of the stent 10 during delivery to the desired arterial location. Other means for securing the stent 10 onto the balloon 14 also may be used, such as providing collars or ridges on the ends of the working portion, i.e., the cylindrical portion, of the balloon 14.

In order to implant the stent 10, it first is mounted onto the inflation balloon 14 on the distal extremity of the delivery catheter 11. In this mounting step, the stent 10 is crimped down onto the balloon 14 to create a low profile. Embodiments of the present invention address this crimping procedure.

The stent-catheter assembly can be introduced into the patient's vasculature through processes known in the art. Briefly, a guide wire 18 is disposed across the arterial section where an angioplasty or atherectomy procedure has been performed and where a follow-up stenting procedure is required. In some cases, the arterial wall lining may be detached so that the guide wire 18 is advanced past the detached or dissected lining 16 and the stent-catheter assembly is advanced over the guide wire 18 within the artery 15 until the stent 10 is directly under detached the lining 16. Prior to inflation of the balloon 14, the delivery sleeve 20 is retracted to expose the stent 10. Depending on the balloon and stent assembly, a delivery sleeve may be unnecessary. The balloon 14 of the delivery catheter 11 then is inflated using an

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inflation fluid. Expansion of the balloon 14 in turn expands the stent 10 against the artery 15. Next, the balloon 14 is deflated and the catheter 11 is withdrawn leaving the stent 10 to support the damaged arterial section. As mentioned above, in order to ensure proper seating of the stent 10 on the balloon 14, and to ensure proper deployment of the stent 10 at the site of the damage within the artery 15, the stent crimping procedure is important.

Embodiments of the present invention are directed to a stent crimping tool that crimps a stent onto a balloon catheter. Preferably, this is accomplished through tangential forces exerted by the tool on the outside surface of the stent to slowly reduce its diameter. The diameter of the stent is continuously reduced until it is stabilized on the balloon catheter.

FIG. 2 provides a perspective view of a preferred embodiment of the stent crimping tool 22. The stent crimping tool 22 is comprised of a base plate 24 to which is mounted at one end a stationary plate 26 and at an opposite end, a platform 28. In the preferred embodiment shown, the stationary plate 26 and the platform 28 are spaced apart from each other. The plates are formed from, or firmly mounted to, the base plate 24 with adhesives or fasteners to prevent relative motion therebetween.

FIG. 5 provides a perspective view of the platform 28 as isolated from the other parts of the stent crimping tool 22. As seen in FIG. 5, the platform 28 preferably includes a channel 30 formed along a length thereof having twin parallel grooves 32 at the base of the channel 30.

A slide 34 is shown both in FIG. 2 and in isolation in the perspective view of FIG. 4. The slide 34 includes a dove tail 72 that is designed to slidably engage the parallel grooves 32 and to slidably move within the channel 30 of the platform 28 in FIG. 5. With preferably tight tolerances in the parts, it is possible to have very precise linear movement of the slide 34 within the channel 30 of the platform 28 with very little lateral play or slop. This minimizes the chance for inconsistent crimps due to unwanted play in the component parts of the crimping tool 22.

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A closing plate 36 preferably is attached to the top of the slide 34 by use of a hinge 38, as best seen in FIG. 2. The hinge 38 permits the closing plate 36 to swing about two positions; namely, the up position as shown by solid lines in the figure, or the down position as shown by dashed lines. The hinge 38 may be loaded with an optional torsion spring, for example, to bias the closing plate 36 toward the up position or the down position as needed.

In an alternative embodiment (not shown), the hinge can be made of a bar of spring steel attached at opposite ends to the slide and the closing plate. When the closing plate swings open or closed, it does so by flexing the bar. Thus, the spring steel bar can be made to resist or to forward bias the closing plate toward either the up or the down position. The bar, of course, may be made from any resilient material known in the art.

Returning to FIG. 2, when the closing plate 36 is in the down position, the underside of the closing plate 36 faces the top side of the stationary plate 26. Optionally, these opposing surfaces are covered with pads 40 and 42. The pad 40 includes two raised ridges 44, 46 while the pad 42 has a single ridge 48. The ridges 44, 46, 48 preferably are aligned along the longitudinal direction as indicated by the arrow A. The arrow A also indicates the direction of translation of the slide 34 relative to the platform 28 and the stationary plate 26, thereby moving the closing plate 36 in its down position to an overlying alignment above the stationary plate 26.

The ridges 44, 46, 48 are intended to engage the rings or the cylindrical elements 12 of the stent 10. Indeed, the stent 10, after being optionally hand crimped to the balloon 14, is inserted laterally in a direction that is generally perpendicular to the direction indicated by the arrow A into the crimping tool 22. Ideally, each ridge 44, 46, 48 engages a corresponding cylindrical element 12 of the stent 10. For example, ridges 44, 46, 48 can be situated to specifically engage distal, proximal, and middle cylindrical elements 12 of the stent 10. To be sure, it

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has been observed that engagement of the ridges 44, 46, 48 against the cylindrical elements 12 of the stent 10 helps to grip the stent 10 during the crimping process.

Optionally, and in order to control the amount of crimp on the stent 10, cylindrical spacers 50 are positioned as shown on the stationary plate 26 in FIG. 2.

5 The diameter of each spacer 50 controls the distance of the gap 52, which defines the distance between the opposing pads 40, 42 of the stationary plate 26 and the closing plate 36, respectively. Controlling the gap 52 thus controls the amount of crimp received by the stent 10. Also, use of spacers 50 to define the size of the gap 52 improves the probability of a precise and repeatable crimp.

10 A force vector F in the general direction as shown in FIG. 2 is applied to the closing plate 36 while it is in the down position. While the force F is applied, the closing plate 36 and the slide 34 translate linearly and reciprocate in the direction along arrow A to perform the crimping process.

Based on the foregoing, it is clear that a theory of operation of a crimping
15 tool 22 according to the invention essentially is two plates 26, 36 sliding against one another. One of the plates 26 can be stationary while the other plate 36 is mounted on a sliding mechanism. The pinching action due to the force F reduces the diameter of the stent 10 while the sliding motion rolls the stent-catheter assembly, as represented by arrow R, to distribute the forces.

20 As mentioned earlier, spacers 50 optionally can be used to control the size of the gap 52. In an alternative embodiment, a mandrel (not shown) can be inserted into the delivery catheter 11 to provide a level of internal resistance in the radial direction to prevent over-crimping of the stent 10 onto the balloon 14. Further, a mandrel can be positioned within the balloon 14 of the catheter 11 during the
25 crimping process to ensure repeatability and a precise crimp of the stent 10.

To use embodiments of the stent crimping tool according to the present invention, the cardiologist lays a stent-catheter assembly, which has been crimped slightly by hand, onto the pad 42 as represented by dashed lines of FIG. 2. The closing plate 36 is moved from its up position to the down position overlying the

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stationary plate 26. Applying the force F, which has been observed to be in the range of two to six pounds, while reciprocating and translating the slide 34 along the direction of arrow A causes the stent-catheter assembly to roll along the direction of arrow R. As the rolling action continues, the force F slowly reduces the diameter of the stent 10 thus crimping it onto the balloon 14 of the catheter 11.

FIGS. 3A and 3B provide perspective views of the pads 54, 56 of alternate embodiments of a stent crimping tool according to the present invention. In the pad 54 of FIG. 3A, there are three ridges 58 corresponding to specific cylindrical elements 12 of the stent 10. As mentioned earlier, these ridges or contours provide grip points on the stent which improve stability during the crimping process.

A stop or riser 60 having vertical surface 62 against which the distal end of the stent 10 abuts helps with alignment of the stent 10 within the stent crimping tool 22. Assuming that the pad 54 is substituted on the closing plate 36 or on the stationary plate 26 in place of the optional pads 40, 42 described above in connection with a preferred embodiment, the pad 54 is oriented such that the ridges 58 are parallel to the ridge 48 on the stationary plate that is shown in FIG. 2. When the stent-catheter assembly is positioned on the pad 54, the distal end of the stent 10 abuts the vertical surface 62 thus aligning the stent 10 lengthwise within the force-transmitting surface area of the pad 54. The riser 60 thus acts as a stop for the stent 10. The height of the riser 60 is low enough to clear the catheter 11 and the guide wire 18 yet still high enough to abut the stent 10.

Likewise, in the alternative embodiment shown in FIG. 3B, the pad 56 includes channels 64 that create raised areas 66 which are intended to engage corresponding cylindrical elements 12 of the stent 10. The pad 56 of FIG. 3B also optionally can include a riser 68 having a vertical surface 70.

Needless to say, the profiles of the ridges 58 or the channels 64 of FIGS. 3A and 3B can have various shapes and dimensions. For example, the ridges may be pointed as in a cone, angled as in a saw-tooth, or rounded. The ridges also may be a

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collection of round pegs bunched closely together to hold the stent. Other conventional geometric shapes are contemplated.

It is preferable that the surface directly in contact with the stent 10 during the crimping process be slightly softer than the material of the stent to allow for yield.

5 Elastomer-type materials with high durometers known in the art can be used for the pads, for example. More precisely, the contoured pads can be made from materials such as that manufactured under the tradename MYLAR by E.I. duPont DeNemours and Co., silicone, rubber, or polycarbonate. The entire crimping tool, or parts thereof, can be made from stainless steel, aluminum, a material manufactured under
10 the tradename DELRIN by E.I. duPont DeNemours and Co., polycarbonate, or the like.

A crimping tool according to the present invention tool preferably is sterilized and intended to be used in a catheterization laboratory by a trained technician or cardiologist. As will be appreciated by those skilled in the art, a
15 crimping tool according to the present invention is designed both for single use applications in a catheterization laboratory by a physician and for multiple use applications in a sterile environment in a high volume manufacturing facility. In such a manufacturing facility where sterile conditions exist, a stent crimping tool according to the present invention can be used repeatedly to crimp stents onto
20 balloons until the mechanism wears out. Thus, repeated uses of the present invention are contemplated for controlled, sterile environments, as are single use applications when operated by catheterization laboratory personnel.

Further, a crimping tool according to the present invention can be used with any stent that is released without a delivery system. The crimping tool also may be
25 sold alone, because its design is robust enough to undergo many uses.

Other modifications can be made to the present invention without departing from the scope thereof. The specific dimensions, procedural steps, and materials of construction are provided as examples, and substitutes are readily contemplated which do not depart from the invention.

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WHAT IS CLAIMED IS:

1. A stent crimping tool for crimping a stent onto a balloon catheter, comprising:

a stationary plate;

a sliding platform, connected to the stationary plate and slidable linearly

5 relative thereto;

a closing plate hinged to the sliding platform so that the closing plate at least partially overlies the stationary plate in a down position, and the closing plate swings away from the stationary plate to an up position;

10 whereby the stent, having been loaded on to the balloon catheter, is placed on the stationary plate from a lateral position, and the closing plate is moved to the down position to hold the stent between the closing plate and the stationary plate, so that an external force on the closing plate and translational motion of the closing plate crimp the stent onto the balloon catheter.

2. The stent crimping tool of claim 1, wherein the closing plate and the stationary plate have facing surfaces that include pads for gripping the stent.

3. The stent crimping tool of claim 1, wherein the stationary plate includes at least one spacer to control a gap between the stationary plate and the closing plate in when the closing plate is moved to the down position.

4. The stent crimping tool of claim 1, wherein the closing plate and the stationary plate have facing surfaces that include opposed contoured pads.

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5. The stent crimping tool of claim 4, wherein the contoured pads include longitudinally oriented ridges.

6. The stent crimping tool of claim 4, wherein at least one contoured pad includes a material selected from the group consisting of MYLAR, silicone, rubber, or polycarbonate.

7. The stent crimping tool of claim 1, wherein the tool includes a material selected from the group consisting of stainless steel, aluminum, DELRIN, or polycarbonate.

8. A stent crimping tool for crimping a stent onto a balloon catheter, comprising:

a base plate having opposed first and second ends;

a stationary plate disposed on the first end of the base plate;

5 a platform disposed on the second end of the base plate, wherein the platform includes a channel;

a slide having a dove tail formation to slidably engage the channel of the platform to enable translation toward and away from the stationary plate;

10 a closing plate hinged to the slide and having a down position at least partially overlying the stationary plate, and capable of swinging away from the stationary plate to an up position; and

whereby the stent, having been loaded on to the balloon catheter, is placed on the stationary plate from a lateral position, and the closing plate is moved to the down position to hold the stent between the closing plate and the stationary plate so

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- 15 that an external force on the closing plate and translational motion of the closing plate crimps the stent onto the balloon catheter.

9. The stent crimping tool of claim 8, wherein the closing plate and stationary plate have facing surfaces each including a pad having a ridge.

10. The stent crimping tool of claim 8, wherein the closing plate and stationary plate have facing surfaces each including a pad having a channel.

11. The stent crimping tool of claim 8, wherein the stationary plate includes a pad having at least two ridges aligned with a proximal ring and a distal ring of the stent.

12. The stent crimping tool of claim 8, wherein the stent crimping tool includes a mandrel disposed inside the balloon catheter.

13. The stent crimping tool of claim 8, wherein the stent crimping tool includes a spring interconnecting the closing plate to the slide.

14. The stent crimping tool of claim 8, wherein the stationary plate includes at least one spacer disposed on a surface facing the closing plate in the down position.

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15. A method for crimping a stent that is pre-loaded onto a balloon catheter, the method comprising the steps of:

- providing a stationary plate;
- providing a sliding platform connected to the stationary plate and slidable
- 5 linearly relative thereto;
- providing a closing plate hinged to the sliding platform so that the closing plate at least partially overlies the stationary plate in a down position, and swings away from the stationary plate to an up position;
- placing the pre-loaded stent and the balloon catheter on the stationary plate
- 10 from a lateral position;
- moving the closing plate to the down position to hold the pre-loaded stent and the balloon catheter between the closing plate and the stationary plate;
- applying an external force on the closing plate to bias the closing plate toward the stationary plate; and
- 15 applying a translational motion to the closing plate thereby crimping the stent onto the balloon catheter.

16. The method of claim 15, wherein the stationary plate includes a ridge and the stent includes a ring, and the method further comprises a step of aligning the ring of the stent with the ridge of the stationary plate thereby crimping the stent onto the balloon catheter.

17. The method of claim 15, wherein the method includes a step of providing a spacer on the stationary plate to set a gap between the stationary plate and the closing plate when the closing plate is in the down position.

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18. The method of claim 15, wherein the external force is between 2 to 6 pounds of force, inclusive.

19. The method of claim 15, wherein the step of moving the closing plate to the down position further comprises rotating the closing plate about a hinged axis located on the sliding platform.

20. The method of claim 15, wherein the method further comprises a step of rotating the pre-loaded stent and balloon catheter.

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FIG. 1

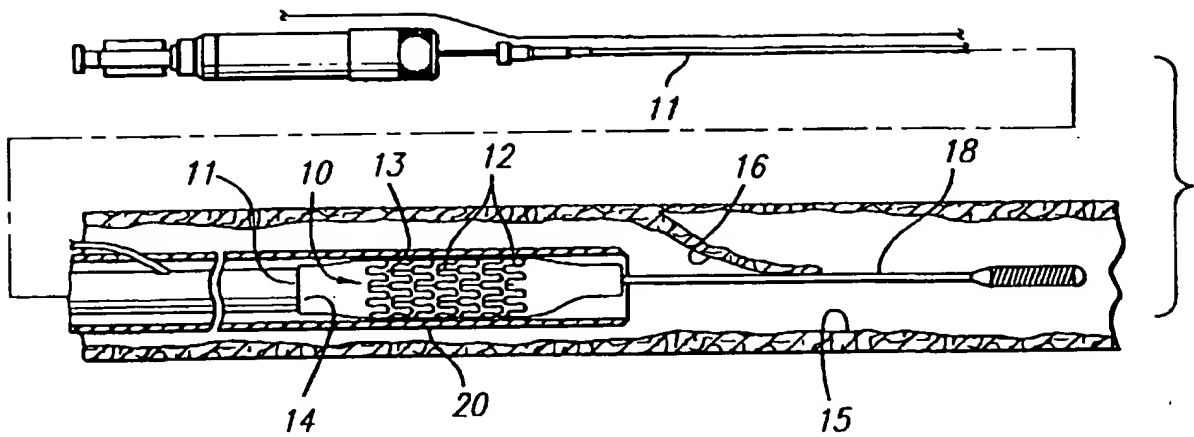
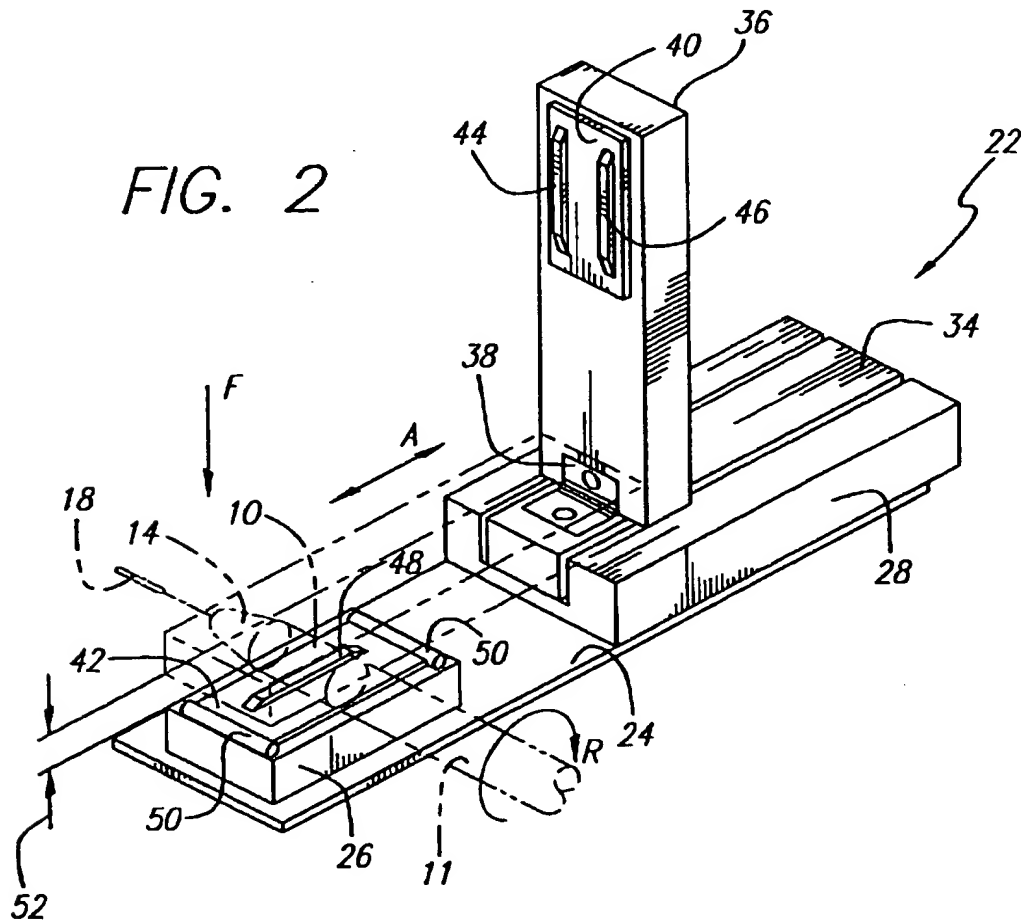


FIG. 2



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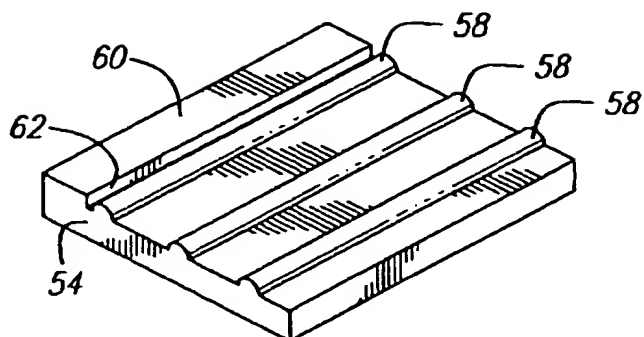


FIG. 3A

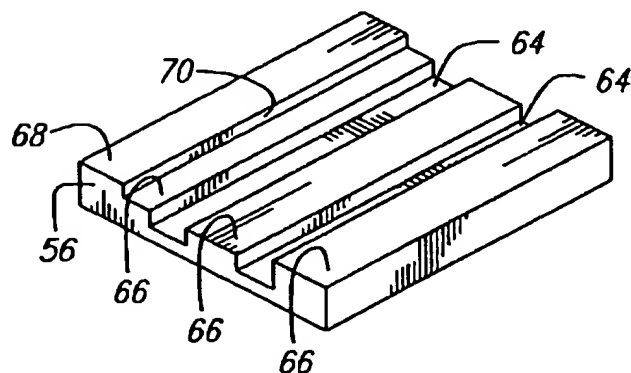


FIG. 3B

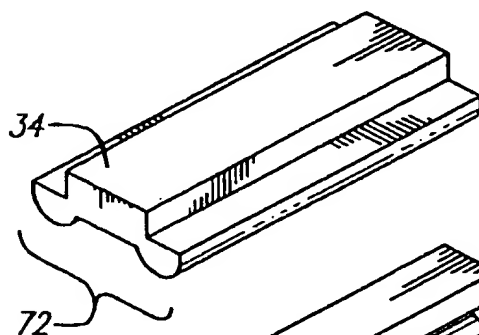


FIG. 4

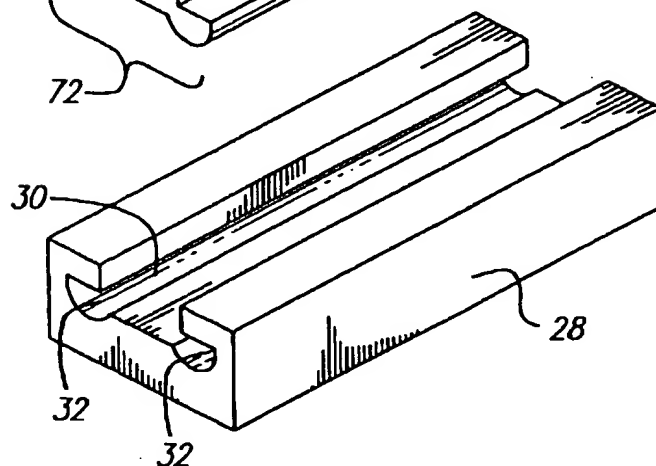


FIG. 5

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INTERNATIONAL SEARCH REPORT

International Application No.

PLI/US 99/17087

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 19633 A (PERCUSURGE INC) 14 May 1998 (1998-05-14) page 9, line 32 -page 10, line 12; figures 1-11 page 8, line 25	1,6,8,15
A	US 5 626 604 A (COTTONE JR ROBERT J) 6 May 1997 (1997-05-06) column 1, line 35 - line 47; figures	1,8,15
A	US 5 672 169 A (VERBEEK MARCEL A E) 30 September 1997 (1997-09-30) abstract; figures	1,8,15

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

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Date of the actual completion of the international search

8 November 1999

Date of mailing of the international search report

12/11/1999

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/17087

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US 5672169 A	30-09-1997	NONE	